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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,845	06/27/2001	Xavier Paliard	1681.002	3705

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EXAMINER	
ANGELL, JON E	
ART UNIT	**PAPER NUMBER**
1635	9

DATE MAILED: 04/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/894,845	Applicant(s) PALIARD, XAVIER	
	Examiner J. Eric Angell	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *16-40 and 42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Comply* .

DETAILED ACTION

Claims 1-42 are pending in the application.

Election/Restrictions

1. Applicant's election without traverse of Group I (claims 1-15 and 41) in Paper No. 8 is acknowledged. Claims 16-40 and 42 are withdrawn from further consideration.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). **For instance, please see specification page 18, second paragraph, which discloses the amino acid sequence "AQALPVWAR" which is designated with a SEQ ID No., and is not present on the Sequence Listing.** This application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825). Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-15 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 41 recite the term, "sustained expression", while claim 3 recited the term, "sustained presence". These terms render the claims vague and indefinite because the specification states, "As used herein, the terms 'sustained expression' and 'sustained presence' in reference to an immunogen, are used to distinguish from expression that is transient. Thus transient expression of with DNA vectors that are not stably maintained is not included within the term 'sustained expression.'" Therefore, it is not clear what constitutes "sustained" as it is only defined as not being transient. There is no clearly defined time when it can be determined that the expression/presence is sustained and not transient.

Additionally, claim 14 recites the phrase, "the method of claim 12, wherein said screening is for agents..." Claim 15 recites, "the method of claim 13, wherein said screening is for agents..." These claims are indefinite because although there is antecedent basis for the methods, claims 12 and 13 are drawn to "non-human animal(s) for screening for agents" wherein the animals are prepared by the methods of claims 1 and 3 respectively. Claims 14 and 15 would be definite if they were amended to depend on the methods in claims 1 and 3.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-13, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (Hepatology; Vol. 31: 1327-1333; June 2000).

Lee et al. teaches a method for preparing a non-human animal for screening for agents that modulate tolerance to an immunogen comprising the steps of

Preparing a nucleic acid directing expression of said immunogen (see p.1328, Plasmids), and

Exogenously delivering said nucleic acid to the liver of said animal (see p. 1328, immunization of animals), under conditions that result in the sustained expression/presence of the immunogen in the liver (see p. 1329, In Vivo Gene Expression; p. 1332, second column, first paragraph; and Fig. 4); wherein the animal is a rodent (for example, see p.1327, Abstract); and

wherein the delivered nucleic acid is not present in the germ line of said animal (see p. 1328, plasmids—the clones are exogenous nucleic acids that were injected into the portal vein, this would not incorporate the nucleic acid into the germline of the animal); and

wherein the nucleic acid is packaged in an adeno-associated virus particle(see p.1328, Plasmids); and

wherein the immunogen is an HCV immunogen (see p.1328, Plasmids); and

wherein the animal is a rodent (see p.1328, Mice); and

wherein the delivery is by portal vein injection (see p.1328, Immunization of Animals); and

wherein the immunogen is the NS5a protein of HCV (see p.1328, Plasmids); and

wherein the animal is tolerant to said immunogen (see p. 1330, first paragraph and Fig. 3).

6. Claims 1, 3, 6, 7, 12, 13 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Feitelson et al. (J. Virol. Vol. 62: 1408-1415).

Feitelson et al. teaches a method for preparing a non-human animal for screening for agents that modulate tolerance to an immunogen comprising the steps of

Preparing a nucleic acid directing expression of said immunogen (see Fig. 1), and

Exogenously delivering said nucleic acid to the liver of said animal (see p.1408, i.h. injections), under conditions that result in the sustained expression/presence of the immunogen in the liver (see p. 1410, Evaluation of Liver Tissue for HBV DNA and pathology); wherein the animal is a rodent (for example, see p. 1408, abstract); and

wherein the delivered nucleic acid is not present in the germ line of said animal (see p. 1408,i.h. injections—the clone is an exogenous nucleic acid that was transfected into the liver, not in the germline of the animal).

7. Claims 1, 3-5 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Yanagi et al. (PNAS, Vol. 94: 8738-3-8743; 1997).

Yanagi et al. teaches a method for preparing a non-human animal for screening for agents that modulate tolerance to an immunogen comprising the steps of

Preparing a nucleic acid directing expression of said immunogen (see p. 8739, Construction of H77 Consensus Chimeric cDNA Clone), and

Exogenously delivering said nucleic acid to the liver of said animal, under conditions that result in the sustained expression/presence of the immunogen in the liver (see p.8742, first three paragraphs); and

wherein the immunogen is a HCV immunogen (for example, see p. 8738, Abstract); and

wherein the delivered nucleic acid is not present in the germ line of said animal(see p. 8740, Intrahepatic Transfection of Chimpanzees—the HCV clone is an exogenous nucleic acid that was transfected into the liver, therefore it is not in the germline of the animal).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

J. Eric Angell
April 8, 2002

JEFFREY FREDMAN
PRIMARY EXAMINER